

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of
Todd PETERSON, et al.
Appln. No.: 10/806,750
Confirmation No.: 2424
Filed: 22 March 2004

Docket No: A9384
Group Art Unit: 2872
Examiner: Joshua L. Pritchett

For: Use Of Light Scattering Particles In Design, Manufacture, And Quality Control Of Small
Volume Instruments, Devices, And Processes

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication is a Request for a Pre-Appeal Brief Conference to formally review
the rejections in the Final Office Action of 12 January 2007.

Basis For Review

1. Applicants request formal review of the rejection of claims 1-5, 7, 8, 18, 19 and 32-35
35 U.S.C. §102(e) as anticipated by United States Patent No. 6,180,415 ("Shultz").

2. Applicants request formal review of the rejection of claim 14-15 under 35 U.S.C.
§103(a) in view of Schultz, and claim 6 under 35 U.S.C. §103(a) in view of Schultz and United
States Patent No. 5,444,529 ("Tateiwa").

Applicants assert that, when Schultz is interpreted properly, the cited reference is
irrelevant to the claimed invention from both an anticipation and obviousness perspective. This
brief will therefore focus on the Schultz reference. In short, the Examiner is improperly
substituting the word "fluid" (as used in the present claims) for the "target" (as used in Schultz).

United States Patent No 6,180,415 ("Schultz")

The present invention is directed towards methods for determining a dynamic property of
a fluid volume in a small volume device comprising determining the distribution or location or
both of at least one resonance light scattering particle in the fluid volume by detecting light

scattered from the light scattering particle(s), wherein the resonance light scattering particle(s) is(are) not specifically bound to another entity. Thus, the methods comprise light scattering particles being distributed within a fluid volume. In addition, the resonance light scattering particles cannot be bound to any other entity within the fluid volume.

Schultz Does Not Teach Fluids

The entire disclosure of Schultz is directed towards the use of plasmon resonance entities (PREs) to detect or provide information about an analyte. Schultz, however, does not disclose or concern itself with resonance light scattering particles to gather information about fluids.

Indeed, very early in disclosure, Schultz makes it clear that its methods are directed towards gathering information regarding analytes, not fluids, when it states that “the aim of analyte diagnostic tests and methods is to detect the presence and/or amount of an analyte (the target).” *U.S. Patent No. 6,180,415*, Col. 1, ll. 18-20. Schultz thus makes it clear to the reader that “target” is synonymous with analyte and not a fluid. This understanding of Schultz is confirmed later in at least two places. First, Schultz states that the methods disclosed therein are used

to interrogate a field for a variety of types of information, including the presence or absence of a target, spatial features of a target, the environment of a target, number and/or spatial distribution of a selected type of target binding sites, and distance relationships in the target

U.S. Patent No. 6,180,415, Col. 9, ll. 18-25. Second, Schultz states that “the target may be any target ... including ... a fluid sample containing a target analyte molecules”

U.S. Patent No. 6,180,415, Col. 14, ll. 49-53. The term target in these passages is used consistent with the term analyte as explicitly disclosed earlier in the patent. And the second passage clearly indicates that a fluid is not a “target,” because the fluid may contain the target.

Interestingly, the Examiner cites one of the passages mentioned above (Col. 9, ll. 18-26) to support his assertion that Schultz teaches methods of gathering fluid dynamics information of a fluid, yet nowhere in this passage does the word fluid appear. To make this passage read on the claimed invention, one would forcibly have to substitute the word “fluid” for the word “target.” Such a substitution would, however, render the passage nonsensical, and there is no clear indication anywhere in Schultz that “target” can or should be substituted for “fluid.” In fact, as stated above, Schultz uses the word

“fluid” very differently from the word “target.” Schultz is therefore clearly informing the reader that its disclosure is directed towards gathering information about analytes (targets) within a given environment or field.

The Examiner also points to another passage within Schultz (Col. 45, ll. 46-55) as an indication that it teaches methods of gathering information about fluid dynamics of a fluid. The Examiner, however, misinterprets the passage, and as a result draws an incorrect conclusion as to what the cited passage would teach one of skill in the art. Indeed, the passage itself states that “a blood cell [analyte] may be labeled and observed in circulation.” *U.S. Patent No. 6,180,415*, Col. 45, l. 45. This first portion of the passage is clearly directed towards observing a labeled blood cell, *i.e.*, a labeled target within the circulation, where circulation can reasonably be interpreted as a fluid. But the passage falls well short of indicating that the methods are used to gather fluid dynamics information of a fluid.

Furthermore, the second portion of the passage upon which the Examiner relies states that “[b]y labeling an entity of interest [analyte] with a PRE, the motion of that entity may be monitored” *U.S. Patent No. 6,180,415*, Col. 45, ll. 50-51 (emphasis added). This second portion is entirely devoid of the word fluid or anything that could reasonably be interpreted to be a fluid. Thus it is unclear how this passage could be used to support an anticipation rejection against the present claims.

Schultz Does Not Teach Fluid Dynamics

The Examiner also utilizes this same passage (Col. 45, ll. 46-55) to support his assertion that Schultz teaches fluid flow rate/patterns (*See* Final Office Action, page 3, line 3 and lines 11-13). Again, this passage focuses on motion of an entity and is entirely devoid of any discussion of fluids, save for a passing reference to the circulation. Furthermore, nothing in the passage or any part of the Schultz disclosure would indicate to one of skill in the art that the word “fluid” can be substituted for the word “target” or “entity.” In fact, the word “flow” is used once in the entirety of Schultz and the phrase “flow rate” is never used; nor can “flow rate” be inferred from any part of the disclosure. Similarly, the phrase “fluid dynamic(s)” is never mentioned in Schultz. Thus, not only is the passage upon which the Examiner relies silent with respect to fluid dynamics, but all of Schultz is silent with respect to fluid dynamics.

The Examiner also asserts that Schultz teaches fluid mixing (*See* Final Office Action, page 3, lines 18-21). Once again, the word fluid does not appear, and the teaching can not be substituted or inferred in the cited passage. The cited passage focuses on cell sorting techniques (FACS) using cells that are labeled with the PREs. The passage can not and should not be interpreted as any type of teaching of fluid dynamics of a fluid.

Schultz Fails to Teach Particles Not Specifically Bound to Another Entity

In every specific embodiment in Schultz, the PREs are bound to some entity, target or analyte. Nowhere does Schultz disclose measuring fluid dynamics (or anything else) using particles that are unbound to another entity. To account for this lack of teaching or even suggestion, the Examiner points to three words in Schultz as evidence that the cited reference discloses methods of utilizing unbound resonance particles. Specifically, the Examiner points to “otherwise distributed therein” as evidence that Schultz teaches the use of unbound resonance particles. Further, the Examiner admits that “this statement may not be enough to teach a specific other distribution,” *Final Office Action of 12 January 2007*, page 6. The Examiner, however, points to no other disclosure in Schultz to support his assertions.

Animal Cells are not The Same as Fluid

The Examiner also asserts that Schultz teaches mixing fluids from two different sources and cites to the same cell sorting passage as discussed previously. The Examiner states that because “[a]nimal cells conform to the outline of their container” they are fluid. *Final Office Action of 12 January 2007*, page 4. As discussed, in the Response to Office Action dated 14 May 2007, cells are comprised of extensive cytoskeletal networks and possess clear distinctive shapes and morphologies, *e.g.*, lymphocytes, fibroblasts, squamous cells, *etc.* If the Examiner’s assertion were correct, all malleable substances and fine-particulate solids, such as table salt or talcum powder would be considered “fluid.” Once again, the Examiner is improperly substituting the word “fluid” in Schultz, in this case as a substitute for animal cells, whenever necessary to maintain the improper rejection. This substitution of fluid for cells is obviously incorrect factually. Because “fluid” should not be substituted for animal cells, Schultz does not teach mixing of two or more fluids.

Schultz Does Not Enable the Presently Claimed Invention

The Supreme Court established long ago that “knowledge supposed to be derived from the [prior] publication must be sufficient to enable those skilled in the art or science to understand the nature and operation of the invention, and to carry it into practical use.” *Seymour v. Osborne* 78 US (11 Wall) 516 at 555 (1870). So, even if one were to improperly substitute target/analyte or entity for “fluid,” and even if one were to improperly assume that three words (“other distributed therein”) indicate particles not being bound to another entity, Schultz would still fail to anticipate the claimed invention. Specifically, Schultz does not teach one of skill in the art how to use resonance particles to measure fluid dynamics of a fluid, which is required in the present case.

Schultz and Tateiwa Fail to Render Obvious The Rejected Claims

As discussed herein, Schultz fails to teach and every element of the claimed invention. The secondary reference, which is cited solely for the improper proposition that light source will cause fluid evaporation, fails to teach the elements missing in Schultz. The statement that “incident light causes fluid to evaporate” is incorrect. It is temperature and pressure that causes liquid to evaporate, as opposed to shining a light into or onto liquid. As discussed previously, the laser in Tateiwa does not cause evaporation. If the laser light in Tateiwas caused evaporation, the entire invention in Tateiwa would be useless because Tateiwa uses a water droplet to scatter light, and the scattered light is subsequently detected. If the laser light in Tateiwa caused the light to evaporate, no light would be scattered and thus no scattered light could be detected.

Accordingly, Applicants believe that, in view of properly construed claims, the Examiner’s rejection of claims 1-5, 7, 8, 18, 19 and 32-35 35 U.S.C. §102(e) under 35 U.S.C. §102(e) is in clear error. Applicants respectfully request reconsideration and withdrawal of the anticipation and obviousness rejections.

Respectfully submitted,

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